

Remarks

Claims 20-36 are pending. Claims 20, 27, 28, and 36 are amended herein to more clearly claim what applicant considers to be his invention. Claim 22 has been canceled. Claims 23, 26, and 29-35 have been withdrawn as drawn to a non-elected invention. Support for these amendments can be found in the original claim language and throughout the specification, as set forth below. It is believed that these amendments add no new matter. In light of these amendments and the following remarks, applicant respectfully requests reconsideration of this application, entry of these amendments and allowance of the claims to issue.

Information Disclosure Statement

The Office Action states that an apparent error on the part of the Office has resulted in one reference, previously submitted in an Information Disclosure Statement in parent Application No. 09/687,459, not being considered. The Office Action states that if applicant provides a legible copy of the missing reference with this response, the reference will be considered.

As requested, applicant submits herewith a clean, unmarked copy of reference A14, listed in the Information Disclosure Statement. Applicant respectfully requests the Examiner to consider this reference and provide a signed copy of the list of references.

Claim Objections

Claims 27 and 28 are objected to because they contain multiple periods (one at the end of each function species).

**ATTORNEY DOCKET NO. 03225.0001U2
APPLICATION NO. 10/650,260**

Claims 27 and 28 are amended by deleting the aforesaid periods and substituting therefor semi-colons. Applicant believes these objections are overcome by these amendments and respectfully requests withdrawal of these objections.

35 U.S.C. § 101

Claim 36 is rejected under 35 U.S.C. § 101 for allegedly being directed to non-statutory matter. Specifically, the Office Action states that claim 36 is drawn to literature consisting of instructions for a method.

Claim 36 is amended herein by deleting the term “instructions” and by reciting the kit comprises the logistic function that is used to combine the serum values of four serum markers selected from a group consisting of α_2 -macroglobulin, AST (aspartate aminotransferase), ALT (alanine aminotransferase), GGT (gammaglutamyl transpeptidase), γ -globulin, total bilirubin, albumin, α_1 -globulin, α_2 -globulin, haptoglobin, β -globulin, apoA1, IL-10, TGF- β 1, apoA2, and apoB. The logistic function is an essential feature for performing the method as claimed in claims 20, 21, 24, 25, 27, and 28. Further, obtaining an end value through the combination of the values of the concentrations of the serum markers by this logistic function makes it possible to determine the presence of an inflammatory, a fibrotic, or a cancerous disease in a tested patient.

Applicant believes that amendment of claim 36 overcomes this rejection. Therefore, applicant respectfully requests withdrawal of this rejection and allowance of amended claim 36.

35 U.S.C. § 112, second paragraph

Claim 36 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Specifically, the Office Action states that claim 36 is indefinite for reciting the term “dosage.”

Claim 36 is amended herein by deleting the term “dosage,” thereby rendering moot this rejection. Therefore, applicant respectfully requests withdrawal of this rejection and allowance of amended claim 36.

35 U.S.C. § 102

A. Claims 20, 21, 22, and 24 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Teare *et al.*, (reference A16 in the Information Disclosure Statement filed October 6, 2003). Specifically, the Office Action states that Teare *et al.* shows a combination of PGA and PIIIP tests that comprise measurements of serological levels of apoA1, GGT, PT, and PIIIP, and that the combined tests are shown to correlate with primary biliary cirrhosis.

Claim 22 is canceled herein, thereby rendering moot this rejection as it applies to this claim. Therefore, applicant respectfully requests withdrawal of this rejection.

Claim 20 is amended herein to include the limitations of claims 22 (canceled herein without prejudice) and 23 (withdrawn). Applicant believes that the inclusion of the limitations of claims 22 and 23 into amended claim 20 overcomes the rejections based on Teare *et al.*, and respectfully requests that these rejections be withdrawn and that amended claim 20 and dependent claims 21 and 24 be allowed.

B. Claims 20, 21, 22, and 24 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Naveau *et al.*, (reference A11 in the Information Disclosure Statement filed October 6, 2003). Specifically, the Office Action states that Naveau *et al.* shows a combination of tests that comprise measurements of serological levels of α -2-macroglobulin, apoAl, GGT, and PT and that the combined tests are shown to correlate with cirrhosis and hepatic fibrosis.

Claim 22 is canceled herein, thereby rendering moot this rejection as it applies to this claim. Therefore, applicant respectfully requests withdrawal of this rejection.

Claim 20 is amended herein to include the limitations of claims 22 (canceled herein without prejudice) and 23 (withdrawn). Applicant believes that the inclusion of the limitations of claims 22 and 23 into amended claim 20 overcomes the rejections based on Naveau *et al.*, and respectfully requests that these rejections be withdrawn and that amended claim 20 and dependent claims 21 and 24 be allowed.

Double Patenting

Claims 20, 21, 22, 24, 25, and 36 are rejected on the ground of non-statutory obviousness-type double patenting as allegedly being unpatentable over claims 1, 2, 3, and 14 of U.S. Patent No. 6,631,330. The Office Action goes on to state that although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 2, 3, and 14 of U.S. Patent No. 6,631,330 are species of instant claims 20, 21, 22, 24, 25, and 36.

Claim 22 is canceled herein without prejudice, thereby rendering moot this rejection as it applies to this claim. Therefore, applicant respectfully requests withdrawal of this rejection.

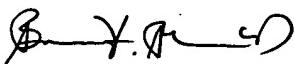
**ATTORNEY DOCKET No. 03225.0001U2
APPLICATION NO. 10/650,260**

While applicant does not concede the Examiner's position, a Terminal Disclosure in compliance with 37 C.F.R. § 1.321(c) is submitted herewith. Applicant, therefore, respectfully asserts that this terminal disclaimer effectively renders moot any obviousness-type double patenting rejections relating to U.S. Patent No. 6,631,330. By submitting this terminal disclaimer, it is understood that applicants do not admit obviousness-type double patenting exists in this case.

A Credit Card Payment Form PTO-2038 authorizing payment in the amount of \$65.00 for a terminal disclaimer fee under 37 C.F.R. § 1.20(d)), and a Terminal Disclaimer are enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.

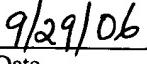

Bruce H. Becker, M.D., J.D.
Registration No. 48,884

NEEDLE & ROSENBERG, P.C.
Customer Number 23859
(678) 420-9300
(678) 420-9301 (fax)

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence, including any items indicated as attached or included, is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.


Bruce H. Becker, M.D., J.D.


Date